Attorney Docket No. IVD 994 US PCT

Applicants note with appreciation the telephonic interview afforded to the undersigned on June 27, 2007, during which the Examiner acknowledged the Examiner's Amendment.

There being no remaining issues, this application is believed in condition for favorable reconsideration and early allowance, and such actions are earnestly solicited.

The Commissioner is hereby authorized to charge any additional fees which may be required by this paper, or credit any overpayment to Deposit Account No. 18-1982.

Respectfully submitted,

July 5, 2007

Date

Kelly L. Bender, Reg. No., 52,610

Attorney for Applicants

sanofi-aventis U.S. LLC Patent Department Route #202-206 / P.O. Box 6800 Bridgewater, NJ 08807-0800 Telephone (610) 889-8995 Telefax (908) 231-2626

Sanofi-Aventis Docket No. IVD 994 US PCT



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspio.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

006497

7590

10/16/2006

ROSS J. OEHLER SANOFI-AVENTIS U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807 **EXAMINER**

JAGOE, DONNA A

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 10/16/2006

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446 601	04/03/2000	BERNARD ABRAMOVICI	IVD994	2604

TITLE OF INVENTION: SOLID PHARMACEUTICAL COMPOSITIONS CONTAINING BENZOFURANE DERIVATIVES

APPLN, TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO '	\$1400	\$0	\$0 .	\$1400	01/16/2007

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

1. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail

Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDEN	ICE ADDRESS (Note: Use Bi	ock i for any change of address)	Fee pape	e: A certificate of main (s) Transmittal. This cer ers. Each additional pap	ng can only be used for tificate cannot be used fo er, such as an assignmen	r any other accompanying t or formal drawing, must
005487 7 ROSS J. OEHLI SANOFI-AVENT 1041 ROUTE 202	ER IS U.S. LLC	/2006	٠,	Certifica	te of Mailing or Transm	
MAIL CODE: D3 BRIDGEWATER						(Depositor's name)
DIGD GD WITTEN	, 110 00007					(Signature)
	•	•				(Datc)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	ATT	ORNEY DOCKET NO.	CONFIRMATION NO.
09/446,601 FITLE OF INVENTION: S	04/03/2000 SOLID PHARMACEU		BERNARD ABRAMOVIC		IVD994 ES	2604
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1400	\$0	\$0	\$1400	01/16/2007
EXAMIN	IER	ART UNIT	CLASS-SUBCLASS			
JAGOE, DO . Change of correspondences CFR 1.363).		I614	514-469000			
Number is required. B. ASSIGNEE NAME AND	attached. ation (or "Fee Address" or more recent) attach D RESIDENCE DATA as an assignee is identi in 37 CFR 3.11. Comp	Indication form ed. Use of a Customer	or agents OR, alternative (2) the name of a single	e firm (having as a mem- agent) and the names of meys or agents. If no na printed. De) atent. If an assignee is assignment.	ther a 2up to	sument has been filed for
a. The following fee(s) are I Issue Fee Publication Fee (No Advance Order - # c	e submitted: small entity discount p	41	b. Payment of Fee(s): (Plea A check is enclosed. Payment by credit can The Director is hereby overpayment, to Depor	se first reapply any pro	tached.	own above)
. Change in Entity Status a. Applicant claims S	•		☐ b. Applicant is no long	per claiming SMALL EN	ITITY status See 37 CFR	
			d from anyone other than the Office.	he applicant; a registered	attorney or agent; or the	assignee or other party in
Toward on painted name				Pagistation No.		
his collection of informatin application. Confidentia ubmitting the completed a bis form and/or suggestion to 1450, Alexandria, Virginia 22313 Under the Paperwork Redu	ion is required by 37 C dity is governed by 35 application form to the s for reducing this bur ginia 22313-1450. DO i-1450. action Act of 1995, no p	FR 1.311. The informatic U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to the NOT SEND FEES OR persons are required to re	on is required to obtain or re 1.14. This collection is est of depending upon the individe Chief Information Office COMPLETED FORMS TO spond to a collection of information	etain a benefit by the puimated to take 12 minute idual case. Any commer, U.S. Patent and Trade THIS ADDRESS. SEN	blic which is to file (and best to complete, including his on the amount of time mark Office, U.S. Depart ID TO: Commissioner for	by the USPTO to process) gathering, preparing, and by you require to complete the to of Commerce, P.O. r Patents, P.O. Box 1450,



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
09/446,601	04/03/2000	BERNARD ABRAMOVICI	IVD994	2604		
005487 7590 10/16/2006			EXAM	EXAMINER		
ROSS J. OEHL	ER		JAGOE, D	ONNA A		
SANOFI-AVEN			ART UNIT	PAPER NUMBER		
1041 ROUTE 20	2-206	•	1614			
MAIL CODE: D			DATE MAILED: 10/16/200	6		
DDIDGEWATE	N I 100017			-		

Determination of Patent Term Extension under 35 U.S.C. 154 (b)

(application filed after June 7, 1995 but prior to May 29, 2000)

The Patent Term Extension is 0 day(s). Any patent to issue from the above-identified application will include an indication of the 0 day extension on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

-	Application No.	Applicant(s)			
	00/446 604	ADDAMOVIOLET AL			
Notice of Allowability	09/446,601 Examiner	ABRAMOVICI ET AL.			
•					
	Donna Jagoe	1614			
The MAILING DATE of this communication apperall claims being allowable, PROSECUTION ON THE MERITS IS therewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT Right of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in this ap or other appropriate communicatio GHTS. This application is subject	opplication. If not included on will be mailed in due course. THIS			
1. $oxed{oxed}$ This communication is responsive to $ extit{RCE and amendment}$	<u>s filed May 24, 2006</u> .				
2. X The allowed claim(s) is/are <u>1-4,6,7,11-13,16 and 19-22</u> .					
 Acknowledgment is made of a claim for foreign priority un a) All Bome Company C		,			
1. Certified copies of the priority documents have					
2. Certified copies of the priority documents have	• • • • • • • • • • • • • • • • • • • •				
3. Copies of the certified copies of the priority doc	cuments have been received in this	s national stage application from the			
International Bureau (PCT Rule 17.2(a)). * Certified copies not received:	•				
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.					
Attachment(s) Notice of References Cited (PTO-892)	5. Notice of Informal I 6. Interview Summary Paper No./Mail Da 7. Examiner's Amend 8. Examiner's Statem 9. Other	y (PTO-413), ate <u>20060929</u> .			

4

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kelly Bender on September 29, 2006.

The application has been amended as follows:

Claim 1. Line 2 of the claim, after the words "antiarrhythmic activity" add the words ---- selected from the group consisting of dronedarone and amiodarone ----.

Claim 4, delete the words "claim 14" and replace with the words — claim 1 ---.

Claim 7, delete the words "claim 15" and replace with the words — claim 6 —.

Cancel claim 14.

Cancel claim 15.

Cancel claim 18

Application/Control Number: 09/446,601

Art Unit: 1614

Claim 19, line 1 of the claim, delete the words "claim 18" and replace with the words --- claim 7 ----.

Claim 19, line 2 of the claim, delete the word "dronedarone" and replace with the word --- amiodarone ----.

Claim 20, line 2 of the claim, after the word "amiodarone" add the word ---- hydrochloride ----.

Claim 20, line 3 of the claim, after the word "dronedarone" add the word ---- hydrochloride ----.

In the specification, Page 11 between lines 17 and 18, insert the words --- BRIEF DESCRIPTION OF THE DRAWINGS ---.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 09/446,601 Page 4

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna yagoe Patent Examiner Art Unit 1614

September 29, 2006

ARDIN H. MARSCHEL SUPERVISORY PATENT EXAMINER

Interview Summary	09/446,601	ABRAMOVICI ET AL.		
interview Summary	Examiner	Art Unit		
	Donna Jagoe	1614		
All participants (applicant, applicant's representative, PT	O personnel):		į	
(1) <u>Donna Jagoe</u> .	(3)			
(2) <u>Kelly Bender</u> .	(4)			
Date of Interview: 29 September 2006.				
Type: a)⊠ Telephonic b)□ Video Conference c)□ Personal [copy given to: 1)□ applicant	2)∏ applicant's repres	entative]		
Exhibit shown or demonstration conducted: d) Yes If Yes, brief description:	e)⊠ No.			
Claim(s) discussed: <u>1,4,7,14,15 and 18-20</u> .	•			
Identification of prior art discussed: none.				
Agreement with respect to the claims f)⊠ was reached.	g)⊡ was not reached.	h) □ N/A.		
Substance of Interview including description of the gene reached, or any other comments: <u>See Continuation She</u>		reed to if an agreeme	nt was	
(A fuller description, if necessary, and a copy of the ame allowable, if available, must be attached. Also, where no allowable is available, a summary thereof must be attack	copy of the amendment	iner agreed would ren s that would render th	der the claims e claims	
THE FORMAL WRITTEN REPLY TO THE LAST OFFICE INTERVIEW. (See MPEP Section 713.04). If a reply to 1 GIVEN A NON-EXTENDABLE PERIOD OF THE LONGE INTERVIEW DATE, OR THE MAILING DATE OF THIS IFFILE A STATEMENT OF THE SUBSTANCE OF THE INTEQUIREMENTS ON TOWN THE SUBSTANCE OF THE INTEQUIREMENTS ON TOWN THE SUBSTANCE OF THE INTEQUIREMENTS ON TOWN THE SUBSTANCE OF THE INTERVIEW OF THE SUBSTANCE OF THE SUB	the last Office action has FR OF ONE MONTH OR NTERVIEW SUMMARY I	aiready been filed, AP THIRTY DAYS FROM FORM, WHICHEVER	PLICANT IS I THIS IS LATER, TO	
		•		
			}	
		•		
•				
Examiner Note: You must sign this form unless it is an			_	
Attachment to a signed Office action.		Examiner's signature, if required		

Application No.

Applicant(s)

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paregraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipuletion, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the Interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by
 attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does
 not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,

(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)

- 6) a general indication of any other pertinent matters discussed, and
- if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Claim 1. Line 2 of the claim, after the words "antiarrhythmic activity" add the words ---- selected from the group consisting of dronedarone and amiodarone ----.

Claim 4, delete the words "claim 14" and replace with the words -- claim 1 ---.

Claim 7, delete the words "claim 15" and replace with the words -- claim 6 ---.

Cancel claim 14.

Cancel claim 15.

Cancel claim 18

Claim 19, line 1 of the claim, delete the words "claim 18" and replace with the words --- claim 7 ----.

Claim 19, line 2 of the claim, delete the word "dronedarone" and replace with the word --- amiodarone ----

Claim 20, line 2 of the claim, after the word "amiodarone" add the word ----hydrochloride ----.

Claim 20, line 3 of the claim, after the word "dronedarone" add the word --- hydrochloride ---...